

Atty. Docket No. PC22004B  
Application No. 10/761,636

### **REMARKS/ARGUMENTS**

In making the rejection 35 USC § 112 the Examiner states that "in an effort to make the record clear, it is noted the below 112 1<sup>st</sup> paragraph rejection is being set forth again...The Examiner amended claim 13 in the Examiner's amendment mailed on 5/9/2006, which obviated the rejection, however, to ensure the claims are amended, the examiner is setting forth the rejection again and respectfully request applicants to provide the claims as amended..."

Applicant hereby amends claims 13 and 19 as suggested by the Examiner. Reconsideration of and withdrawal of this rejection in view of the amendments is respectfully requested.

**35 USC § 103(a) Harvey (WO 1998/06407) and Lukas et al. (US 2002/0028780) in view of  
Andrews et al. (US 4,988,696)**

Lukas relates to topical formulations containing an avermectin such as selamectin. Harvey relates to non-topical uses of praziquantel. In particular, Harvey relates to oral drenches containing praziquantel. A drench is not a topical application of a drug, but instead, is an oral formulation. It is respectfully submitted that the person skilled in the art would not turn to Harvey to find suggestion of possible topical formulations. In other words, it is not proper to combine Harvey with Lukas et al. Reconsideration and withdrawal of this rejection under 35 USC § 103(a) is respectfully requested.

Andrews et al. relates to praziquantel formulations. Accordingly, the combination of Harvey and Andrews et al. does not disclose applicants' invention of a topical formulation containing both praziquantel and selamectin. According to the examiner, Lukas et al., teach a topical antiparasitic formulation comprising an avermectin or milbemycin having endo- or extoparasitic activity, an ether, optionally an antioxidant, and a solvent. The examiner also asserts that Andrews et al. teach of topical formulations and methods of treating worm diseases by applying praziquantel.

The Examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the active agents selamectin and praziquantel, to form a single composition with these references before them and use them as an anthelmintic. Further, the Examiner alleges that, "one would have been motivated to combine the active agents because it is obvious to combine two compositions each of which is used for the same purpose, to form a

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new composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art."

As the Examiner points out on page 6 of the most recent office action "claims 13-18 are drawn to methods of treating or preventing flea or heartworm infections, or treating tapeworm infections by administering the formulation of claim 1." Applicant submits that it would not have been obvious to one of ordinary skill in the art at the time of the invention to combine a selamectin composition of Lukas with a praziquantel composition of Andrews to treat or prevent flea infection, since it is not disclosed in Andrews nor is it taught in the art that praziquantel is useful for treating and/or preventing flea infection. It would also not have been obvious at the time of the invention to combine a selamectin composition of Lukas with a praziquantel composition of Andrews to treat or prevent heartworm infection, since it is not disclosed in Andrews nor is it taught in the art that praziquantel is useful for treating and/or preventing heartworm infection. Further, it would not have been obvious to one of ordinary skill in the art at the time of the invention to combine a selamectin composition of Lukas with a praziquantel composition of Andrews to treat tapeworm infection, since it is not disclosed in Lukas nor is it taught in the art that selamectin is useful for treating tapeworm infection.

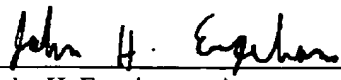
Clearly, praziquantel compositions of Andrews, which are disclosed for treatment of parasitic tapeworms, and selamectin compositions of Lukas, which are disclosed for treatment of fleas and heartworm, are not, in fact, used "for the very same purpose." Additionally, neither Andrew's composition nor Lukas's composition is used for the very same purpose that composition(s) of the current invention, that is, treating or preventing flea or heartworm infections, or treating tapeworm infections.

Further, there is no way that the synergy, surprisingly discovered by Applicant for treatment of the tapeworm (dipylidium), for composition(s) of the current invention comprising selamectin (at a dose of 8 mg/kg) and praziquantel (at a dose of 1 mg/kg), could have been anticipated by one of ordinary skill in the art at the time of the invention. Data demonstrating this synergy is presented on page 4 of the present specification. The combination praziquantel and selamectin show a synergy that is not expected based upon Lukas et al. or Andrews et al or a combination of these references. This unexpected synergy supports the patentability of the present invention. Prompt and favorable consideration of this application and allowance thereof is respectfully requested. If the Examiner believes that personal communications will expedite

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prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

  
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